

**Experiment Number:** 20008-02  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** Milk thistle extract  
**CAS Number:** 84604-20-6

**Date Report Requested:** 10/15/2014  
**Time Report Requested:** 18:05:46  
**First Dose M/F:** NA / NA  
**Lab:** SRI

<b>C Number:</b>	C20008
<b>Lock Date:</b>	11/08/2002
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF MILK THISTLE EXTRACT**

**MALE MOUSE**

**Organ**

Kidney: Renal Tubule

Testes

**FEMALE MOUSE**

**Organ**

Adrenal Cortex

Liver

Pancreas

Stomach, Forestomach

**Morphology**

Regeneration Focal

Atrophy

**Morphology**

Vacuolization Cytoplasmic

Inflammation Chronic Focal

Cyst

Hyperplasia Focal

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Adrenal Cortex</b>						
<b>Accessory Adrenal Cortical Nodule</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Adrenal Cortex</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
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 Species/Strain: Mouse/B6C3F1

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Eye: Retrobulbar</b>						
<b>Inflammation Acute Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
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 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Kidney</b>						
<b>Hydronephrosis</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Kidney</b>						
<b>Infiltration Cellular Lymphocyte Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	10%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	93(T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	P=0.760	P=0.500N	P=0.500N
POLY 1.5	(e)	(e)	(e)	P=0.760	P=0.500N	P=0.500N
POLY 6	(e)	(e)	(e)	P=0.760	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.231N	(e)	(e)	P=0.763N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=1.000	P=0.159N	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Kidney: Renal Tubule Regeneration Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.043*	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.067
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



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 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Liver</b>						
<b>Depletion Glycogen</b>						
<b>LESION RATES</b>						
OVERALL(a)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
POLY-3 RATE (b)	4/10.00	0/0.00	0/0.00	0/0.00	0/0.00	6/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	0%	60%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
FIRST INCIDENCE	93(T)	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.333
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.333
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.333
COCH-ARM / FISHERS	P=0.251	(e)	(e)	(e)	(e)	P=0.328
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.194
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Liver</b>						
<b>Inflammation Chronic Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	30%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	93(T)	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.678
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.678
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.678
COCH-ARM / FISHERS	P=0.596	(e)	(e)	(e)	(e)	P=0.686N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Lung</b>						
<b>Hemorrhage Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Lung</b>						
<b>Infiltration Cellular Lymphocyte Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Lymph Node, Mesenteric</b>						
<b>Degeneration Lymphoid Diffuse</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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 Species/Strain: Mouse/B6C3F1

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Pancreas</b>						
<b>Cyst</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Parathyroid Gland</b>						
<b>Cyst</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Forestomach</b>						
<b>Erosion Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 6	P=0.107	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.075	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Forestomach</b>						
<b>Hyperplasia Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.086	(e)	(e)	(e)	P=0.227	P=0.500
POLY 1.5	P=0.086	(e)	(e)	(e)	P=0.227	P=0.500
POLY 6	P=0.086	(e)	(e)	(e)	P=0.227	P=0.500
COCH-ARM / FISHERS	P=0.089	(e)	(e)	(e)	P=0.237	P=0.500
MAX-ISO-POLY-3	P=0.107	(e)	(e)	(e)	P=0.067	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Forestomach</b>						
<b>Ulcer</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	93(T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.584	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.356	(e)	(e)	(e)	P=0.159	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Forestomach</b>						
<b>Ulcer Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Glandular Cyst</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.196	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Testes</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	1/1.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	93(T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.091	(e)
COCH-ARM / FISHERS	P=0.700	(e)	(e)	(e)	P=0.091	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.000**	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Thymus</b>						
<b>Degeneration Lymphoid Diffuse</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Thyroid Gland</b>						
<b>Ectopic Thymus</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Adrenal Cortex</b>						
<b>Accessory Adrenal Cortical Nodule</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/1.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.288	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Adrenal Cortex</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
OVERALL(a)	3/10 (30%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	3/10.00	0/1.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	0%
TERMINAL (d)	3/10 (30%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	P=0.689N	(e)	(e)	(e)	P=0.095N
POLY 1.5	(e)	P=0.689N	(e)	(e)	(e)	P=0.095N
POLY 6	(e)	P=0.689N	(e)	(e)	(e)	P=0.095N
COCH-ARM / FISHERS	P=0.068N	P=0.727N	(e)	(e)	(e)	P=0.105N
MAX-ISO-POLY-3	(e)	P=0.330N	(e)	(e)	(e)	P=0.025N*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Eye: Retrobulbar</b>						
<b>Inflammation Acute Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Kidney</b>						
<b>Hydronephrosis</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Kidney</b>						
<b>Infiltration Cellular Lymphocyte Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Kidney: Renal Tubule</b>						
<b>Regeneration Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Liver</b>						
<b>Depletion Glycogen</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.416N	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
POLY 1.5	P=0.416N	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
POLY 6	P=0.416N	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.415N	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.075N	P=0.159N	P=0.159N	P=0.159N	P=0.159N	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Liver</b>						
<b>Inflammation Chronic Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	3/10 (30%)	10/10 (100%)	9/10 (90%)	9/10 (90%)	8/10 (80%)	10/10 (100%)
POLY-3 RATE (b)	3/10.00	10/10.00	9/10.00	9/10.00	8/10.00	10/10.00
POLY-3 PERCENT (g)	30%	100%	90%	90%	80%	100%
TERMINAL (d)	3/10 (30%)	10/10 (100%)	9/10 (90%)	9/10 (90%)	8/10 (80%)	10/10 (100%)
FIRST INCIDENCE	93(T)	93(T)	93(T)	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.012*	P=0.000**	P=0.003**	P=0.003**	P=0.024*	P=0.000**
POLY 1.5	P=0.012*	P=0.000**	P=0.003**	P=0.003**	P=0.024*	P=0.000**
POLY 6	P=0.012*	P=0.000**	P=0.003**	P=0.003**	P=0.024*	P=0.000**
COCH-ARM / FISHERS	P=0.030*	P=0.002**	P=0.010**	P=0.010**	P=0.035*	P=0.002**
MAX-ISO-POLY-3	P=0.000**	P=0.000**	P<0.001**	P<0.001**	P=0.007**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Lung</b>						
<b>Hemorrhage Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Lung</b>						
<b>Infiltration Cellular Lymphocyte Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Lymph Node, Mesenteric Degeneration Lymphoid Diffuse</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	30%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	93(T)	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.292
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.292
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.292
COCH-ARM / FISHERS	P=0.201	(e)	(e)	(e)	(e)	P=0.291
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.138
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Pancreas</b>						
<b>Cyst</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/1.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	100%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	93(T)	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	P=0.091	(e)	(e)	(e)	(e)
POLY 1.5	(e)	P=0.091	(e)	(e)	(e)	(e)
POLY 6	(e)	P=0.091	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.366N	P=0.091	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	P=0.000**	(e)	(e)	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Parathyroid Gland</b>						
<b>Cyst</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Forestomach</b>						
<b>Erosion Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Forestomach</b>						
<b>Hyperplasia Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.012*	(e)	(e)	(e)	P=0.227	P=0.227
POLY 1.5	P=0.012*	(e)	(e)	(e)	P=0.227	P=0.227
POLY 6	P=0.012*	(e)	(e)	(e)	P=0.227	P=0.227
COCH-ARM / FISHERS	P=0.014*	(e)	(e)	(e)	P=0.237	P=0.237
MAX-ISO-POLY-3	P=0.021*	(e)	(e)	(e)	P=0.067	P=0.067
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Forestomach</b>						
<b>Ulcer</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Forestomach</b>						
<b>Ulcer Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 6	P=0.107	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.075	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Stomach, Glandular Cyst</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.500N	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500N	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.267N	(e)	(e)	(e)	P=0.500N	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.159N	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Thymus</b>						
<b>Degeneration Lymphoid Diffuse</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20008-02  
 Test Type: 90-DAY  
 Route: DOSED FEED  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 10/15/2014  
 Time Report Requested: 18:05:46  
 First Dose M/F: NA / NA  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
Thyroid Gland						
Ectopic Thymus						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

**Experiment Number:** 20008-02  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
**Test Compound:** Milk thistle extract  
**CAS Number:** 84604-20-6

**Date Report Requested:** 10/15/2014  
**Time Report Requested:** 18:05:46  
**First Dose M/F:** NA / NA  
**Lab:** SRI

**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (n) No statistics are calculated if all dose groups have fewer than two tumors.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

**\*\* END OF REPORT \*\***